REMARKS

1. Statement of the Interview

Applicants appreciate the courtesies extended by the Examiners to Applicants' Representative during the interview on February 25, 2009. At that time, all of the rejections were discussed. The Examiners indicated that Applicants' Response of February 3, 2009 should be sufficient to overcome the rejections under 35 U.S.C. § 112 and § 102. The rejection of the claims under 35 U.S.C. § 103 for obviousness was discussed. No agreement was reached, although the Examiners requested some further clarification of the test results reported in the Zanellato Declaration that was submitted with the Response.

2. Further Comments on Comparative Test Results

During the interview of February 25, 2009, the Examiners requested clarification of the test results reported in the Zenallato Declaration, particularly the test results as summarized in the graphs of Attachments 1 and 2 of the Declaration. The following comments are offered in response to those questions, and are supported by the attached Zanellato Declaration 2.

2.1 The Test Results in the Graph of Attachment 2 – The Examiners questioned the meaning of the results in the graph of Attachment 2 entitled "Areas of scarring: % of treated areas vs control (untreated areas)". The Examiners particularly questioned why the areas of scarring for samples A and B are low on day 1, but then are about equal to samples C and D on day 3, but then are again reduced at days 14 and 42. The Examiners also questioned why it appears that the scarring for samples A and B seems to become worse from day 1 to day 3, but then improves between days 3 and 14. The explanation is provided in paragraphs 7.1-7.4 of the enclosed Zanellato Declaration 2. In summary, the differences observed at days 1, 3, 14 and 42 must also be considered in combination with the art recognized three major phases of the wound healing process. (See for example, Exhibit 1 attached to the Zanellato Declaration 2) Samples A and B show an increased area of scarring from day 1 to day 3 because at that time the inflammatory components of the healing process are most prevalent. However, by day 14 the

proliferation phase of the healing process is dominant and the positive effect of the present invention on samples A and B can be observed.

2.2 Test Results Reported in Attachment 1 – The Examiners also requested some further explanation of the results reported in the graph of Attachment 1, namely the graph entitled "Effect of hyaluronate formations on wound coverage". The response to this query is supported by paragraph 8 of the Zanellato Declaration 2. In summary, the graph of Attachment 1 shows that tests D and E according to the present invention exhibited increased wound coverage (namely improved re-epithelialization of the wound area); whereas, the comparative test samples A, B and C showed wound coverage values that were either about the same as control or were actually less than control. In other words, wound healing was significantly improved by use of the samples according to the present invention; whereas, there was no positive effect observed by means of the comparative test samples.

In order to quantify the improved results achieved by the present invention, paragraph 8 of the Zanellato Declaration 2 presents numerical values for the observed wound coverage of the samples in Attachment 1 of the Zanellato Declaration. From these results it can be seen that the samples according to the present invention (samples D and E) showed an improvement of about 40% in wound coverage as compared to all of the control samples.

2.3 Explantation of the Types of Scarring – The Examiners also questioned the meaning of the different types of scarring recited in the claims. In particular, referring to the claims submitted with the Amendment on 3 February 2009, claim 3 was directed to a method for treatment to reduce "the extent of normotrophic scarring on the skin", claim 4 was directed to a method "for reducing the extent of wounds to the skin", claim 14 was directed to a method "for treating scarring of the skin" and claim 18 was directed to a method "for the treatment of normotrophic scarring on the skin". As explained in the Specification, the present invention is generically directed to the treatment of cutaneous scars (see page 1, lines 5-8 of the Specification); and specifically directed to reducing the extent of normotrophic scarring (see for example page 5, lines 5-7 of the Specification). Cutaneous scarring is understood as a generic term to encompass various types of scarring, including normotrophic scarring, hypertropic

scarring, keloid scanning and other types of recognized scars. (See for example, attached Exhibits 2, 3 and 4) While animal models are available to test treatments for scarring, there does not appear to be agreement in the art with regard to accepted standard models for evaluating treatments of these specific types of scarring. (See, e.g., Exhibits 5, 6 and 7) However, the Applicants believe that the model utilized in the present application (see Example 1 beginning on page 27) and in Attachment 2 of the Zanellato Declaration, is appropriate for measuring the effect of treatment on normotrophic scarring. Hence, it is believed that the test results support claims to both the generic term "cutaneous scarring" and to specifically "normotrophic scarring". In addition, the test results reported in Attachment 1 of the Zanellato Declaration specifically measured the effect of formulations on wound healing as measured by the length of epidermal coverage or re-epithelialization of the wound area. Applicants submit that this test data supports claims, such as claim 4, directed to a method for reducing the extent of wounds to the skin.

The enclosed Abatangelo Declaration further supports the comments provided in the Zanellato Declaration 2, and the patentability of the present invention.

In view of the above, in combination with the enclosed Zanellato Declaration 2, the enclosed Abatangelo Declaration, and Applicants' Response filed on 3 February 2009, it is submitted that all of the rejections have been overcome, so that all the claims should now be in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections and early allowance of all the claims are requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

If the Examiner has any questions concerning this application, the Examiner is requested to contact Leonard R. Svensson, Reg. No. 30,330 at the telephone number of (858) 792-8855. Facsimile communications may be sent to Leonard R. Svensson at the facsimile number of (858) 792-3785.

Dated: March 9, 2009

Respectfully submitted,

By

Leonard R. Svensson
Registration No.: 30,330
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive
Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant